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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,923	10/14/2003	Sankar Chatterjee	CEPH-2313	7061
23377	7590	08/04/2004	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/685,923

**Applicant(s)**

CHATTERJEE ET AL.

**Examiner**

Rita J. Desai

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-43 is/are pending in the application.
- 4a) Of the above claim(s) 27,38 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-and 43 is/are rejected.
- 7) ☒ Claim(s) 39 and 40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/21/03</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Priority***

A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

***Election/Restrictions***

Applicants elected group

- X. Claims 20 and 21 in part drawn to compounds, as given in table 4, not included in group I-IV, wherein the R has a piperazine classified in class 544 and various subclasses.

Claims 1-12, 14, 15, 20, 21, 25 and 26 were canceled.

New claims 27-43 have been added.

New Claims 39 and 40 now read on the elected group X.

See applicants remarks

With respect to the response to the Restriction Requirement, wherein applicants elected with traverse to prosecute the claims of Group X (claims 20 to 21 drawn to compounds as given in Table 4, not included in Groups I to IV, wherein the R has a piperazine), applicants submit that this election now applies with equal force to new claims 39 and 40.

The new claims 39 and 40 are being examined herewith.

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Applicants arguments that the applicants have a considerable core is not found to be persuasive.

See below:-



=> s 13

SAMPLE SEARCH INITIATED 17:08:06 FILE 'REGISTRY'

SAMPLE SCREEN SEARCH COMPLETED - 1602 TO ITERATE

62.4% PROCESSED 1000 ITERATIONS 50 ANSWERS

INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE \*\*COMPLETE\*\*

BATCH \*\*COMPLETE\*\*

PROJECTED ITERATIONS: 29640 TO 34440

PROJECTED ANSWERS: 5304 TO 7446

When a preliminary search was done on the core it gave numerous iterations which indicates that the core is not novel and not applicants contribution over the prior art of record.

Hence restriction is proper.

Applicants request to rejoin the method claim 43 has been considered and examiner is rejoining it since claim 39 is dependent on claim 27 and claim 43 is dependent on claim 27.

Claims 42 and 43 are being rejoined limited in scope to the claim 39 and 40 .

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***Claim Objections***

Claims 42 and 43 are objected to because of the following informalities: They do not depend from the elected group claim 39 or 40. Appropriate correction is required.

Also claim 39 and 40 depend from a non-elected claim. Applicant should write them in independent form.

Also the claim 42 which is composition, applicants are required to insert a pharmaceutical composition.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some IC50 values for inhibition, does not reasonably provide enablement for what this inhibition utility is. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

There is little predictability in the art that all compounds inhibit a receptor site or not.

There is no guidance provided as to what it indicates since the values given for the compounds range from 10 to 4000.!

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Applicants have a laundry list of diseases in their background information relating the proteases and various diseases.

The art is highly unpredictable. Drugs do not have an umbrella efficacy and hence the inhibitory values with such a wide range is misleading since it would also depend on numerous other conditions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a method of inhibiting a serine or cysteine protease, without indicating the subject who would need the inhibition.

It is unclear what this inhibition utility is .

This is a reach through claim wherein the claim does not disclose a well defined utility. It is not clear what the claims intent to inhibit is.

Is it an assay invitro test and if it is in-vivo then how does one know the effect?

If in vivo applicants should rewrite the claim with specific diseases so that one would know the effect.

If it is an assay applicants have not provided the different steps.

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***Conclusion***

The compounds of claim 39 and 40 are found to be allowable , however claims 42 and 43 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684.

The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai  
Primary Examiner  
Art Unit 1625

R.D.  
July 29, 2004

*R. Desai*  
7/29/04